An Ovine Model for Exclusive Endoscopic Ear Surgery

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Conflict of Interest

The authors declare no conflict of interest.

Authors' contributions

LA and MB: conception and design; anatomical and surgical dissection, data collection and analysis; manuscript edition, revision and approval. MG: conception and design; anatomical dissection; manuscript revision and final approval. FM and DV: conception and design; anatomical dissection, surgical supervision; manuscript revision and approval. MC and LP: conception and design, senior supervision and critical revision of dissection; manuscript revision and approval. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Abstract

Importance: With the international spread of exclusive transcanal endoscopic ear surgery the need for a suitable and affordable surgical training model has grown over the last years.

Objective: We aimed to develop and validate an ex-vivo animal model for exclusive endoscopic ear surgery.

Design: Experimental study

Setting: Temporal bone laboratory

Methods: We compared the ovine and human middle ear anatomy in 4 specimens and assessed the lamb as a model for endoscopic ear surgery. After confirming its suitability, we developed a surgical training program for canaloplasty, myringoplasty and ossiculoplasty. From March to May 2016 the ex-vivo model was tested assessing the time needed for dissection and complications. Each experience was subjectively validated on a scale from 1 (worst) to 10 (best).

Results: We assessed the suitability of our novel lamb model on a total of 20 ovine middle ears. All interventions could be performed in a satisfactory way. The time required for canaloplasty and tympano-meatal flap elevation decreased from initially 46.4 (first 5 cases) to 16.2 minutes (last 5 cases) during dissection representing an absolute difference of 30.2 minutes (95% CI: 22.28 – 38.12). The subjective feedback revealed excellent values.

Conclusion: The ovine model is suitable for endoscopic ear surgery. We describe here a novel, exclusively endoscopic approach in an ex-vivo animal model for middle ear surgery. The proposed surgical program leads the trainee step-by-step through the main otologic procedures and is able to enhance its surgical skills.

Key words: Ovine model; lamb model; endoscopic ear surgery; middle ear anatomy; myringoplasty; ossiculoplasty

Introduction

The exclusive transcanal endoscopic approach to the middle ear was introduced and developed during the last decades [1]. As for all surgical procedures adequate training of surgical skills during cadaveric dissection courses is advisable. It enhances the dexterity and provides experience, which is required for a successful performance during future interventions. In fact, surgical simulation has become a valuable and financially attractive part of surgical education with a beneficial effect on competency and patient's safety [2]. Fresh human cadaveric specimens are the gold standard of surgical training, though its availability is limited due to high costs and local regulations. The animal model represents a suitable, cheap and reliable alternative. The safety of the ovine model has recently been described for a multitude of procedures in head and neck surgery [3].

In otologic surgery the sheep has been described and validated for the training of stapes surgery [4,5], for implantable devices [6] and for the round window insertion of cochlear implants [7]. Comparative anatomy studies allowed identifying similarities and differences between the sheep and the human middle ear [8]. Its suitability was confirmed by comparative radiological studies [9]. In conclusion the ovine model is suitable to train and develop surgical skills in an education program for otologic surgeons.

A main issue in developing an animal model for exclusive endoscopic ear surgery is the incongruence to the human anatomy in particular of the external auditory canal (EAC). In our experience one of the most difficult steps in the exclusive endoscopic approach is the raise of the tympano-meatal flap and the maneuvering of the instruments in a possibly bent and narrow EAC. An animal model should meet these difficulties in order to provide adequate training.

The aim of this study is to compare the human and the ovine endoscopic anatomy and to develop a suitable ovine model for exclusive endoscopic ear surgery. In a second phase we aim to apply and validate the model.

Material and Methods

We performed dissection on fresh or previously defrosted (24h at ambient air) 6 months old lamb heads by the means of 3 mm diameter, 15 cm length, endoscopes (Karl Storz, Tuttlingen, Germany) with angles of 0 and 45°, a three-CCD camera system and a high-resolution monitor (Karl Storz). The surgical equipment for temporal bone dissection including a drill is required. Specimens were obtained at the local butcher from animals intended for the sale of their meat. Our Institutional Review Board approved the use of fresh ex-vivo ovine heads for the present study. Animal welfare was subject to agricultural and veterinary regulations.

Anatomical studies

Two fresh ovine heads were used for anatomical dissection of the EAC and the middle ear (n=4). Moreover, we performed a CT scan to improve our understanding of the anatomical particularities of this model.

The external ovine ear is covering the external meatus and must be partially amputated in order to access the EAC. The cartilaginous part of the EAC is posteriorly bent. When applying anterior traction to the remnant external ear and the cartilaginous EAC the bony part of the EAC can easily be accessed. A dominant bony prominence in the EAC hinders the direct access to the tympanic membrane (TM) as illustrated endoscopically and radiologically in Figure 1. After removal of the obstacle the TM can be assessed. Comparing to the human anatomy, the very thin membrane presents a large pars flaccida posterior and superior to the malleus, covering the epitympanic space. During the raise of the tympano-meatal flap (TMF) we were surprised by the lack of an annulus in all specimens.

The ovine middle ear is fairly similar to the human (Figure 2). However, we identified some important differences: the malleus lies more anteriorly and has a long handle, which is attached to the inferior-anterior floor of the tympanic cavity (TC). The body of the malleus is thin and fragile and presents several ligaments, as well as the insertion of a very large tensor tympani muscle medially. The incus is of similar shape to the human with a short and a long process articulating with the stapes. Unlike Cordero et al [10], we identified only one stapedial tendon. The facial nerve was always dehiscent but in a similar position as in humans. The retro- and hypotympanum containing the round window are hidden behind a bony prominence of the EAC and show almost no pneumatization (compare CT scan on Figure 1).

Surgical Model

After thorough anatomical evaluation we created a step-by-step guide to the exclusive surgical dissection of the ovine ear performing different routine procedures in otologic surgery as following:

A. Preparation (Figure 3): The aim of the first preparative step is to permit suitable endoscopic access to the bony part of the EAC. The ovine head is placed on a clean dressing. It is very important to orient the nose of the sheep superiorly (12 o'clock), to perform the dissection in a surgical position. The external ear is cut at about 2 cm from its insertion on the skull. In case of a large bulging of the tragus, it can be removed. Two tension sutures through the cartilaginous part of the EAC are placed:

the first anteriorly and the second inferiorly through the cartilaginous EAC. The small hairs in the EAC are then cut. By the means of the endoscope and suction tube a thorough cleaning of the EAC is performed, followed by the inspection of the anatomical landmarks.

B: Creating the tympano-meatal flap and consecutive canaloplasty (Figure 4): The TMF is delineated. Two horizontal incisions in the skin are placed posterio-superiorly at the lateral end of the pars flaccida (9 o'clock) and anterio-inferiorly at about 4 o'clock. These are reunited by a vertical incision on the EAC floor laterally on the bulging bony crest. The flap is created strictly following the bone using a dissector and cotton swabs. Once the bony bulging is free of skin it can be removed using a sharp standard otologic drill. We suggest protecting the flap with a cotton swab from the drill. The most lateral and inferior part of the canal may also be enlarged in order to allow better maneuvering of the instruments. The more experience the trainee has, the less enlargement of EAC is necessary.

During this part of the dissection, the handling of the endoscope concomitant to the instrument in the EAC may be difficult for a novice endoscopic ear surgeon but will improve with growing expertise. One principal quality of the otologic surgeon can be trained in this phase: patience.

The access to the tympanic cavity is then performed beginning on the lateral end of the pars flaccida. After proper dissection of the pars flaccida the ossicles are identified and dissected (Figure 2). A posterior spine with the emergence of the chorda tympani can be identified.

C: Endoscopic myringoplasty/epitympanoplasty (Figure 5A+B): The TM is carefully detached from the posterior part of the malleus and the TMF positioned anteriorly.

The dimension of the large attic is assessed by the means of a hook and an artificial membrane (COOK Medical Biodesign ®) or a piece of cartilage and perichondrium from the external ear is created respectively. The graft is positioned on the dissected malleus and the flap finally repositioned. Advanced surgeons may try to perform myringoplasty for anterior perforations, representing a more challenging dissection.

D: Endoscopic incus interposition ossiculoplasty (Figure 5C+D): First the incudo-stapedial joint is identified and disarticulated by a hook, by the following the posterior ligaments of the incus are detached from the epitympanic wall and as third step the incudomalleolar articulation is mobilized with gentle movements. The incus is then removed from the tympanic cavity, fixed in a small clamp and tailored by a diamond burr. The removal of the short and long process is required to create a rectangular bony block. A small hole on one side is created to match the head of the stapes. The shaped incus is then repositioned on the stapes.

Validation of the Model

The surgical model was assessed on a total of 20 ears by two ENT surgeons with 4 years of experience each (LA and MB). The time to perform the different steps and possible complications met in real surgery were assessed. After each dissection every surgeon had to provide adequate subjective feedback rating the quality and the learning experience on a scale from 1 (very bad) to 10 (excellent) and underwent external evaluation by a senior surgeon.

The statistical analysis was performed using GraphPad Prism® software. A nonparametric Kruskal-Wallis test was used to analyze the improvement of time required to perform the different steps. To this end we formed chronological groups of 5 dissections, comparing the mean values ± standard deviation (SD) using a multiple comparisons model. A p value ≤ 0.05 was considered significant. Results were reported as effect sizes showing the absolute difference between the compared variables and 95% CI around the difference.

Results

All 20 specimens were successfully dissected from March to May 2016. The mean time required to perform canaloplasty was 30 minutes (SD: 13.23), for middle ear dissection 8 minutes (SD: 2.6), for myringoplasty 8 minutes (SD: 4.3) and for ossiculoplasty 10 minutes (SD: 2.7). Figure 6 summarizes the evolution of the different steps in terms of "operating time" over the training experience. We observed a considerable drop of time required for canaloplasty. The improvement was assessed statistically significant comparing the first to the last group of five interventions. Required dissection time dropped from initially 46.4 (first 5 cases) to 16.2 minutes (last 5 cases), representing an absolute difference of 30.2 minutes (95% CI: 22.28 – 38.12) as shown in Figure 7. The duration of the other surgical steps (middle ear dissection, myringoplasty and ossiculoplasty) was almost constant over the whole experience and differences statistically not significant.

The observed complications during dissection were 9 perforations of the TM or the TMF, 1 section of chorda tympani and 3 subluxations of the incudomalleolar joint. The stapes remained intact in all cases.

The model met the expectations of the performing surgeons. The subjective rating revealed excellent values for tissue quality (8.9 points out of 10), overall satisfaction (8.3/10) and the learn effect (8.8/10). The different steps were also very positively rated as summarized in Figure 8. The external rating revealed values from 6 to 10 with a mean at 7.4 points out of 10.

For teaching purposes, a tutorial video was edited, which is accessible as online supplement to this manuscript.

Discussion

The ex-vivo ovine model for ear surgery presented in this study is an exclusively endoscopic approach, which has not been described before. Surgical education requires time and resources in order to allow the trainee to improve his skills under supervision of an experienced surgeon. It has been shown that residents need one and a half time longer to complete a tympanoplasty type I compared to attending physicians [11]. A logical observation, as every manual task is improved by experience, which may be acquired in the operating room. We have to consider that the numbers of performed surgical procedures by residents are limited, due to work-time regulations, economic consideration and also the safety of the patient has to be taken into account [12]. Therefore, the use of ex-vivo training models is widely practiced in otologic surgical procedures, e.g. by the means of a temporal bone dissection laboratory [13]. However, the access to human cadaveric specimens may be limited due to financial or regulatory issues. In this situation, the animal model helps out as a valid alternative.

The ovine model serves as a cheap and reliable model for otologic surgery. The life-like feeling of fresh specimens provides excellent tissue properties and dissection. Another advantage is the similar size and presentation of the gross anatomical structures compared to humans [3-5]. The learning curve in endoscopic ear surgery may be somewhat different [14] and therefore a proper model for exclusive endoscopic ear surgery is required. The use of an endoscope and therefore visualization of the performed dissection on a screen improves the supervision and feedback of the supervising faculty member. Both trainee and tutor have the same field of view, therefore teaching is straightforward and the suggestions or corrections can directly be addressed.

Regarding the literature Cordero at al [10] described recently a model for training endoscopic stapedectomy. In this study the complete amputation of the cartilaginous part of the EAC and drilling of the bony EAC under microscopic view is suggested. In comparison our model has the advantage of managing the ovine EAC and the creation of a TMF in a purely endoscopic way. This is in our opinion an essential difference. The delicate maneuvering of the instruments in the EAC, which limited space is further compromised by the presence of the endoscope needs specialized training. To this end we took advantage of the slightly bend ovine ear canal with a bony prominence. The required enlargement of the EAC is performed under endoscopic view, representing excellent training for endoscopic canaloplasty. In our experience during various dissection courses, the endoscopic drilling is a very challenging task for a novice in endoscopic ear surgery and needs proper training. The correct endoscopic creation of a TMF and enlargement of the EAC is met by our model of exclusive endoscopic ear surgery.

The anatomical differences to the human middle ear represent the main limitation of this model. For instance, the absence of an annulus separating the TM from the mucosa of the middle ear creates some supplementary difficulties to the trainee. The elevation of the TMF is surely hindered, since a main landmark is missing. Another important difference to the setting in the operating room is the missing of bleeding in the present ex-vivo model. We feel that the training under simplified conditions is suitable especially for a novice to ear surgery. The experience gained in the concomitant and delicate handling of the endoscope and the surgical tools in the EAC and the middle ear are considerable. The overall subjective satisfaction of the performing surgeons dissecting the proposed surgical program was very high as summarized in Figure 8. However, this rating has not been evaluated before and represent therefore only the surgeons experience. The validity of our model is rather represented by the statistically significant decrease of required dissection time for TMF creation and canaloplasty indicating its suitability as an animal model for endoscopic ear surgery.

Conclusion

The ovine model is suitable for endoscopic ear surgery. We describe a novel, exclusively endoscopic approach in an ex-vivo animal model for middle ear surgery. The proposed surgical program leads the trainee step-by-step through the main otologic procedures and is able to enhance its surgical skills.

Acknowledgements

Authors' contributions: LA and MB: conception and design; anatomical and surgical dissection, data analysis; manuscript edition, revision and approval. MG: conception and design; anatomical dissection; manuscript revision and final approval. FM and DV: conception and design; anatomical dissection, surgical supervision; manuscript revision and approval. MC and LP: conception and design, senior supervision and critical revision; manuscript revision and approval. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

LA and MB had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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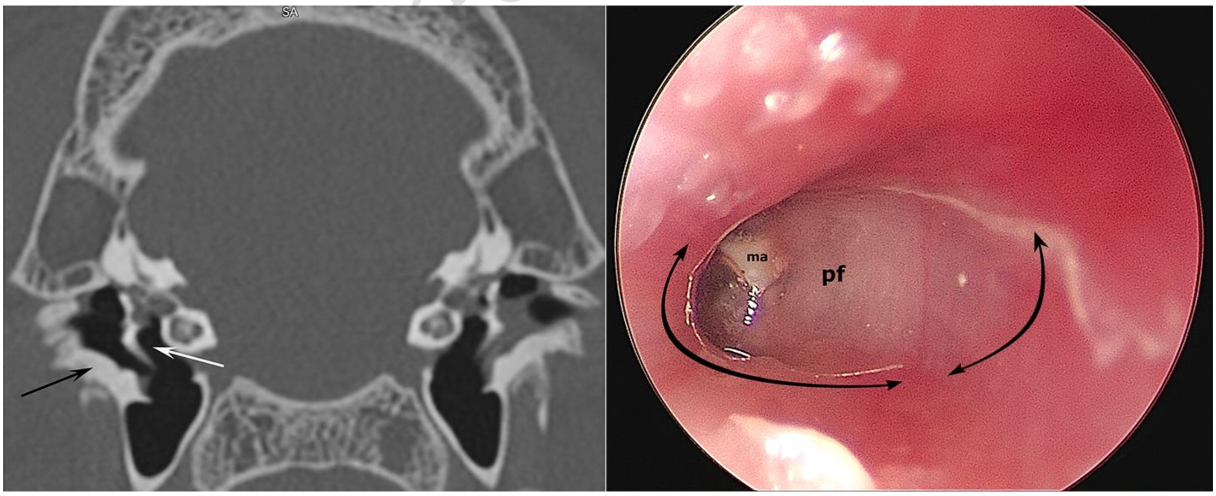
Figure Legends



A B

Figure 1

Endoscopic and Radiologic Evaluation of the right ear

A: CT scan showing the anatomical peculiarities of the ovine model. Black arrow: bony prominence of the external auditory canal (EAC), white arrow: long handle of the malleus. Panel B: endoscopic view of the same ear. Black arrows indicate direction and extent of the required drilling; ma: malleus and pf: pars flaccida.

Figure 2

Title: External Specimen Preparation

Legend: Right ear. The ovine head is placed with the nose directed superiorly (12 o' clock) and the external ear is cut about 2 cm from its insertion on the skull. Two tension sutures are placed to enlarge the cartilaginous part of the EAC.

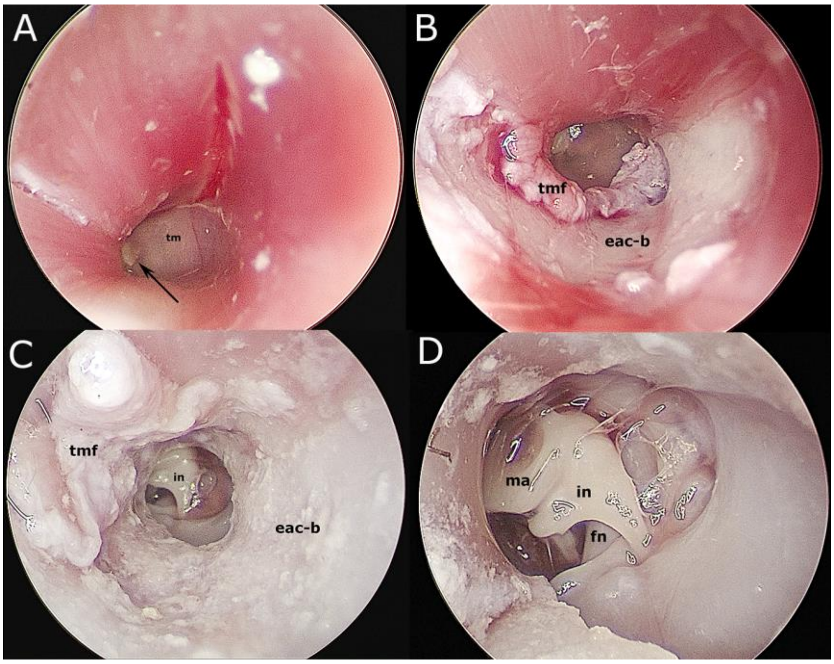


Figure 3

Title: Canaloplasty and Tympano-Meatal Flap Elevation

Legend: Right ear. Panel A: endoscopic view on the horizontal incisions in the EAC skin. Black arrow indicates the malleus. Panel B: endoscopic view. Tympano-meatal flap elevation. Panel C: endoscopic view. Access to the tympanic cavity after dissection of the pars flaccida. Panel D: endoscopic view. Exploration of the ossicles in the tympanic cavity.

ma: malleus, tmf: tympano-meatal flap, eac-b: bone of the external auditory canal, in: incus, fn: facial nerve

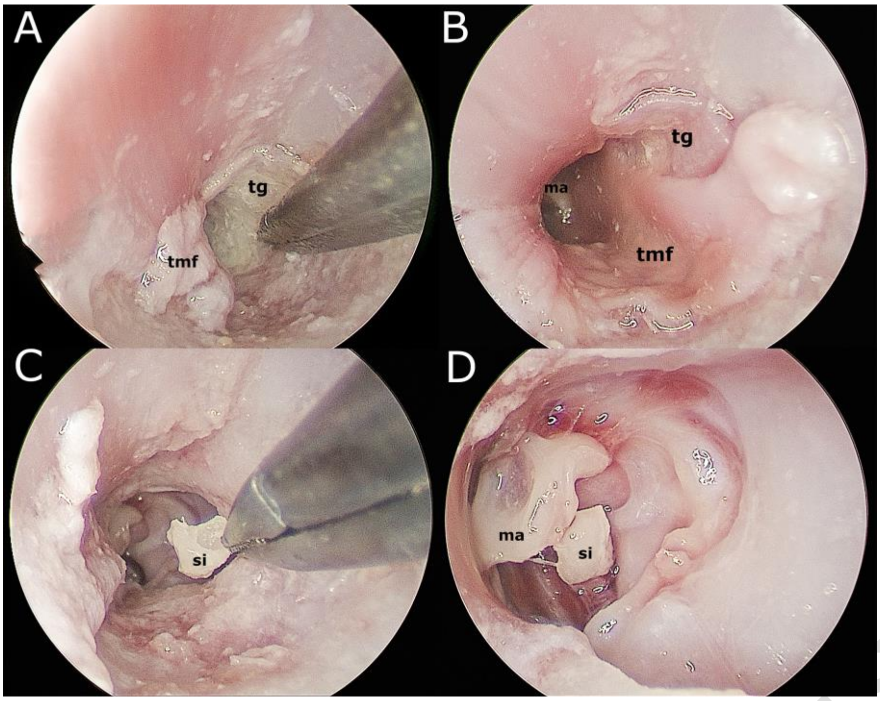


Figure 4

Title: Myringo- and Ossiculoplasty

Legend: Right ear. Panel A and B: endoscopic view. Myringoplasty procedure. The artificial membrane is positioned on the dissected malleus and the tympano-meatal flap is then repositioned. Panel C and D: endoscopic view. Ossiculoplasty procedure. The shaped incus with a small hole to match the head of the stapes is repositioned between the stapes and the malleus.

tg: tympanic graft, tmf: tympano meatal flap, ma: malleus, si: shaped incus

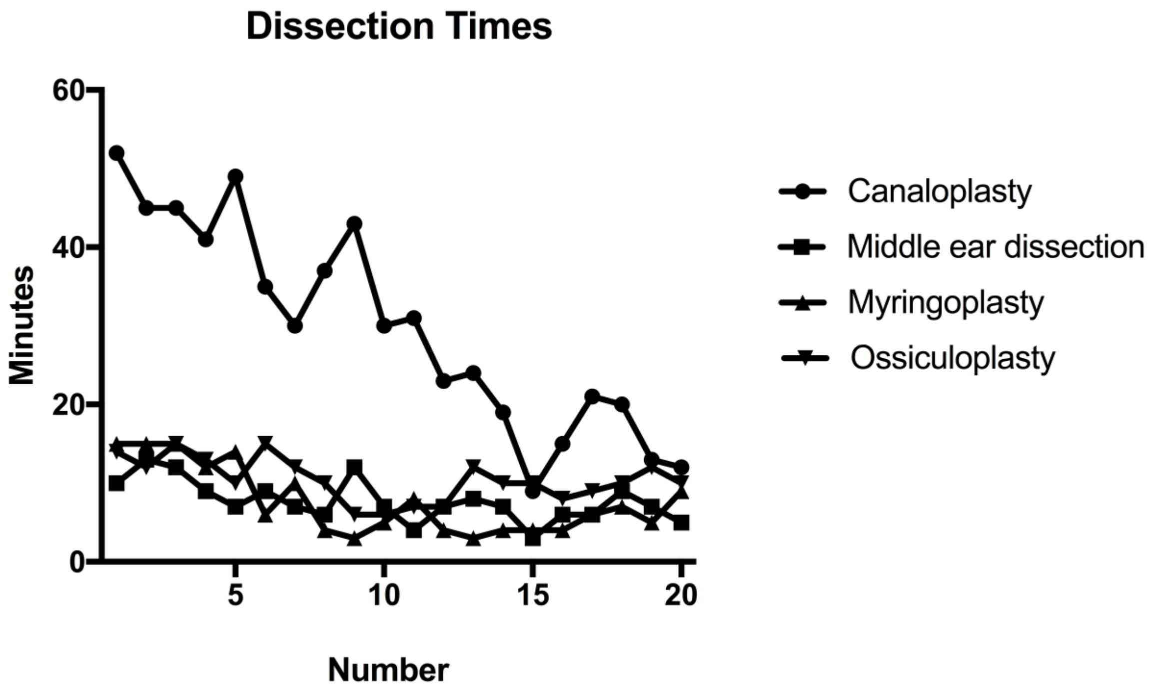


Figure 5

Title: Assessment of Dissection times

Legend: Chronological surgical times over dissection evaluation of the different steps of the surgical model.